WE CLAIM:

1. A storage-stable topical pharmaceutical shampoo comprising:

about 0.5-8% by weight of an active ingredient comprising an antimicrobial agent or a pharmaceutically acceptable salt thereof;

about 0.5-30% by weight of at least one surfactant selected from the group consisting of an amphoteric surfactant, an anionic surfactant, and mixtures thereof;

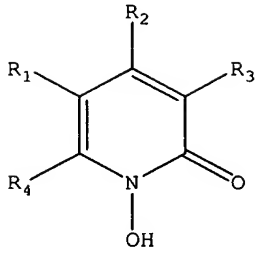
about 0.01-1% by weight of at least one chelating agent;

about 40-90% by weight of purified water; and

sufficient amounts of at least one pH modifier selected from the group consisting of pharmaceutically acceptable acids, bases, and mixtures thereof to provide the pharmaceutical shampoo with an overall pH of about 3.0 to about 8.0;

wherein said active ingredient maintains a concentration of degradation product(s) less than about 5% of the starting concentration of said active ingredient.

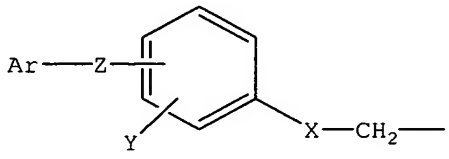
2. The shampoo of claim 1, wherein said antimicrobial agent is a compound having the formula I:



I

or a pharmaceutically acceptable salt thereof, wherein:

R_1, R_2, and R_3, which are identical or different, are H or alkyl having 1 to 4 carbon atoms, and R_4 is a saturated hydrocarbon radical having 6 to 9 carbon atoms or a radical of formula II:



II

where:

X is S or O;

Y is selected from the group consisting of H, 1 or 2 identical halogen atoms, and a mixture of 2 different halogen atoms;

Z is selected from the group consisting of a single bond and a bivalent radical comprising O, S, CR_2 where R_2 is H or (C_1-C_4)-alkyl, or from 2 to 10 carbon atoms linked in the form of a chain, which optionally further comprises one or more of the following:

(i) a carbon-carbon double bond, or

(ii) O, S, or a mixture thereof, wherein if 2 or more O or S atoms or a mixture thereof are

present, each O or S atom is separated by at least 2 carbon atoms; and,

in any of the foregoing bivalent radicals, free valences of the carbon atoms of said bivalent radical are saturated by H, (C_1-C_4)-alkyl, or a mixture thereof; and

Ar is an aromatic ring system having one or two rings that can be substituted by one, two, or three radicals, which may be identical or different, which are selected from the group consisting of halogen, methoxy, (C_1-C_4)-alkyl, trifluoromethyl, or trifluoromethoxy.

3. The shampoo of claim 2, wherein said antimicrobial agent is selected from the group consisting of 6-[4-(4-chlorophenoxy)-phenoxymethyl]-1-hydroxy-4-methyl-2-pyridone, 1-hydroxy-4-methyl-6-cyclohexyl-2-pyridone, 1-hydroxy-4-methyl-6-(2,4,4-trimethylpentyl)-2-pyridone, a pharmaceutically acceptable salt thereof, and a mixture thereof.

4. The shampoo of claim 3, wherein said antimicrobial agent is 1-hydroxy-4-methyl-6-cyclohexyl-2-pyridone or a pharmaceutically acceptable salt thereof.

5. The shampoo of claim 1, wherein said antimicrobial agent possesses anti-inflammatory

properties.

6. The shampoo of claim 1, wherein said antimicrobial agent possesses activity against microbes selected from the group consisting of gram positive bacteria, gram negative bacteria, funguses, molds, viruses, and combinations thereof.

7. The shampoo of claim 1, wherein said active ingredient has a concentration of degradation product(s) less than about 2% of the starting concentration of said active ingredient.

8. The shampoo of claim 1, comprising about 1 to about 5% by weight of said active ingredient.

9. The shampoo of claim 1, wherein said shampoo possesses anti-inflammatory properties.

10. The shampoo of claim 1, wherein said at least one surfactant comprises at least one amphoteric surfactant and at least one anionic surfactant.

11. The shampoo of claim 10, wherein said amphoteric surfactant is cocoamidopropyl betaine.

12. The shampoo of claim 10, wherein said anionic surfactant is triethylamine lauryl sulfate.

13. The shampoo of claim 1, comprising about 12-22% by weight of said at least one surfactant.

14. The shampoo of claim 1, wherein said chelating agent is disodium edetate.

15. The shampoo of claim 1, wherein said shampoo has a pH of about 5.5 to about 7.0.

16. The shampoo of claim 15, wherein said shampoo has a pH of about 6.5.

17. The shampoo of claim 1, wherein said pH modifier is selected from the group consisting of sodium hydroxide, citric acid, and a mixture thereof.

18. The shampoo of claim 1, further comprising about 0.1-5% by weight of at least one conditioning agent.

19. The shampoo of claim 18, wherein said conditioning agent affects the physical properties of a surface to which said shampoo is applied.

20. The shampoo of claim 19, wherein said surface is selected from the group consisting of populated hair, hair follicles, a surface contiguous to or in close proximity to hair, sweat glands, sebaceous glands, and combinations thereof.

21. The shampoo of claim 18, wherein said conditioning agent is a hair conditioning agent.

22. The shampoo of claim 21, wherein said hair conditioning agent is selected from the group consisting of a silicone compound, a quaternary ammonium compound, a fatty compound, a lanolin or a derivative thereof, and mixtures thereof.

23. The shampoo of claim 22, wherein said hair conditioning agent is a mixture of cetrimonium chloride and ethoxylated polyethylene glycol lanolin.

24. The shampoo of claim 21, comprising about 0.5-2.5% by weight of said at least one hair conditioning agent.

25. The shampoo of claim 1 which further comprises an additional ingredient selected from the group consisting of a humectant, inorganic salt, fragrance,

dye, hair colorant, foam stabilizer, preservative, water softening agent, and mixtures thereof.

26. The shampoo of claim 1 which further comprises a thickener selected from the group consisting of methylcellulose, hydroxybutyl methylcellulose, hydroxypropylcellulose, hydroxypropyl methylcellulose, hydroxyethyl ethylcellulose, hydroxyethylcellulose, di(hydrogenated tallow)phthalic acid amide, crosslinked maleic anhydride-methyl vinyl ether copolymer, guar gum, xanthan gum, gum arabic, and mixtures thereof.

27. A method of treating a skin or hair disorder in a mammal, comprising administering to skin or hair of a mammal in need thereof a therapeutically effective amount of a storage-stable topical pharmaceutical shampoo comprising:

about 0.5-8% by weight of an active ingredient comprising an antimicrobial agent or a pharmaceutically acceptable salt thereof;

about 0.5-30% by weight of at least one surfactant selected from the group consisting of an amphoteric surfactant, an anionic surfactant, and mixtures thereof;

about 0.01-1% by weight of at least one chelating agent;

about 40-90% by weight of purified water; and

sufficient amounts of at least one pH modifier selected from the group consisting of pharmaceutically acceptable acids, bases, and mixtures thereof to provide the pharmaceutical shampoo with an overall pH of about 3.0 to about 8.0;

wherein said active ingredient maintains a concentration of degradation product(s) less than about 5% of the starting concentration of said active ingredient.

28. The method of claim 27, wherein said skin or hair is selected from the group consisting of populated hair, hair follicles, a surface contiguous to or in close proximity to hair, sweat glands, sebaceous glands, and combinations thereof.

29. The method of claim 27, wherein the administration of said shampoo cleans hair or scalp of said mammal.

30. The method of claim 27, wherein said skin or hair is natural or synthetic skin or hair.

31. The method of claim 27, wherein the administration of said shampoo reduces the number of microbes on hair or scalp of said mammal.

32. The method of claim 31, wherein said microbes are pathogenic.

33. The method of claim 31, wherein said microbes are selected from the group consisting of bacteria, funguses, molds, viruses, and combinations thereof.

34. The method of claim 33, wherein said bacteria is selected from the group consisting of gram positive bacteria, gram negative bacteria, and combinations thereof.

35. The method of claim 34, wherein said gram positive bacteria are selected from the group consisting of *Streptococcus* sp., *Micrococcus* sp., *Staphylococcus* sp., *Bacillus* sp., and combinations thereof.

36. The method of claim 35, wherein said *Streptococcus* sp. are selected from the group consisting of *S. viridans*, *S. agalactiae*, *S. pyogenes*, *S. faecalis*, *S. durans*, *S. faecium*, *S. mutans*, *S. sanguis*, *S. salivarius*, *S. mitior*, *S. constellatus*, *S. intermedius*, *S. anginosus*, *S. milleri*, *S. iniae*, *S. pneumoniae*, and combinations thereof.

37. The method of claim 35, wherein said *Staphylococcus* sp. are selected from the group consisting of *S. aureus*, *S. epidermidis*, and combinations thereof.

38. The method of claim 33, wherein said fungus is selected from the group consisting of *P. ovale*, *P. versicolor*, *M. furfur*, *T. beigelii*, *B. capitatus*, *P. marneffei*, *C. neoformans*, *S. prolificans*, *S. shenkii*, *Epidermophyton floccosum*, *Microsporum canis*, *Candida* sp., *Trichophyton* sp., and combinations thereof.

39. The method of claim 38, wherein said *Candida* sp. are selected from the group consisting of *C. albicans*, *C. cruzii*, *C. krusei*, *C, glabrata*, *C. guillermondii*, *C. inconspicua*, *C. parapsilosis*, *C. tropicalis*, and combinations thereof.

40. The method of claim 38, wherein said *Trichophyton* sp. are selected from the group consisting of *T. rubrum*, *T. mentagrophytes*, *T. tonsurans*, *T. violaceum*, and combinations thereof.

41. The method of claim 33, wherein said mold is selected from the group consisting of *Aspergillus* sp., *B. dermatitidis*, *P. brasiliensis*, and combinations thereof.

42. The method of claim 41, wherein said *Aspergillus* sp. are selected from the group consisting of *A. flavus*, *A. fumigates*, *A. niger*, and combinations thereof.

43. The method of claim 27, wherein said skin or hair disorder is selected from the group consisting of dandruff, seborrheic dermatitis, itchy flaky scalp conditions, pityriasis versicolor, tinea pedis, tinea cruris, tinea corporis, cutaneous candidiasis, and combinations thereof.

44. A storage-stable topical pharmaceutical shampoo comprising:

about 0.5-8% by weight of an active ingredient comprising ciclopirox or a pharmaceutically acceptable salt thereof;

about 0.5-30% by weight of at least one surfactant selected from the group consisting of an amphoteric surfactant, an anionic surfactant, and mixtures thereof;

about 0.01-1% by weight of at least one chelating agent;

about 40-90% by weight of purified water; and

sufficient amounts of at least one pH modifier selected from the group consisting of citric acid, sodium hydroxide, and mixtures thereof to provide the pharmaceutical shampoo with an overall pH of about 5.5 to

about 7.0;

wherein said active ingredient maintains a concentration of degradation product(s) less than about 5% of the starting concentration of said active ingredient.

45. The shampoo of claim 44, further comprising about 0.1-5% by weight of at least one hair conditioning agent selected from the group consisting of cetrimonium chloride, ethoxylated polyethylene glycol lanolin, and mixtures thereof.

46. The shampoo of claim 44, wherein said active ingredient has a concentration of degradation product(s) less than about 2% of the starting concentration of said active ingredient.

47. The shampoo of claim 44, wherein said at least one surfactant is selected from the group consisting of cocamidopropyl betaine, triethylamine lauryl sulfate, and mixtures thereof.

48. A method of treating a skin disorder in a mammal, comprising administering to a mammal in need thereof a therapeutically effective amount of a storage-stable topical pharmaceutical shampoo comprising:

about 0.5-8% by weight of an active ingredient comprising ciclopirox or a pharmaceutically acceptable salt thereof;

about 0.5-30% by weight of at least one surfactant selected from the group consisting of an amphoteric surfactant, an anionic surfactant, and mixtures thereof;

about 0.01-1% by weight of at least one chelating agent;

about 40-90% by weight of purified water; and

sufficient amounts of at least one pH modifier selected from the group consisting of citric acid, sodium hydroxide, and mixtures thereof to provide the pharmaceutical shampoo with an overall pH of about 5.5 to about 7.0;

wherein said active ingredient maintains a concentration of degradation product(s) less than about 5% of the starting concentration of said active ingredient.

49. A process for preparing a storage-stable topical pharmaceutical shampoo, said process comprising:

1) preparing an aqueous phase comprising about 40 to about 90% by weight of the overall weight of the composition of water and a first surfactant at a temperature of about 73 to about 93 ^{0}C,

2) cooling said aqueous phase to a temperature of

about 44 to about 65 ^{0}C while mixing;

3) adding a first surface conditioning agent and at least one chelating agent to said aqueous phase one at a time while mixing until said aqueous phase has a uniform appearance;

4) cooling said aqueous phase to a temperature of about 22 to about 42 ^{o}C;

5) preparing an active ingredient solution comprising a second surfactant and about 0.5-8% of the overall weight of the composition of an active ingredient comprising an antimicrobial agent or a pharmaceutically acceptable salt thereof at a temperature of about 22 to about 42 ^{o}C;

6) adding said active ingredient solution to said aqueous phase;

7) adding sufficient amounts of at least one pH modifier to provide said aqueous phase with a pH of about 5.5 to about 7.0; and

8) recovering a storage-stable topical pharmaceutical shampoo.

50. The process of claim 49, wherein said first surfactant is an anionic surfactant.

51. The process of claim 49, wherein said process step 1) further comprises adding at least one thickening

agent and a second surface conditioning agent to said aqueous phase prior to addition of said first surfactant, and mixing until all ingredients are melted.

52. The process of claim 49, wherein between said step 2) and said step 3), samples of said aqueous phase are collected and slowly poured back into said aqueous phase while observing for unhydrated particles.

53. The process of claim 52, wherein said aqueous phase is mixed for at least a further fifteen minutes if unhydrated particles are observed until said unhydrated particles are no longer observed.

54. The process of claim 49, wherein said second surfactant is an amphoteric surfactant.

55. The process of claim 49, wherein said active ingredient solution is prepared by mixing for at least 70 minutes until dissolution of said active ingredient is complete without generating foam during said preparation.

56. The process of claim 49, wherein said aqueous phase is mixed for at least fifteen minutes after said active ingredient solution is added thereto.

57. The process of claim 49, wherein said at least one pH modifier is selected from the group consisting of sodium hydroxide, citric acid, and a mixture thereof.